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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/876,091 | 06/08/2001 | Klaus-Ulrich Weithmann | 02481.1748 | 9372 |

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EXAMINER

GITOMER, RALPH J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

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DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,091

Applicant(s)

Weithmann

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 10, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The amendment received 2/6/03 and the RCE Request received 3/10/03 have been entered, claims 1 and 3 are considered here.

5 In view of the arguments presented and amendments to the claim, the rejection of record under 35 USC 103(a) is hereby withdrawn because the references do not teach determining whether a substance inhibits or acts as a ligand of the binding domain specifically.

10 Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly
15 connected, to make and/or use the invention.

The claims as amended are directed to determining if a test substance inhibits or acts as a ligand of a binding domain specifically. As claimed, one cannot determine if the test
20 substance inhibits or acts as a ligand of the binding domain, the catalytic domain or both.

The written description in the specification as originally filed fails to teach one of skill how to accomplish this. On page 3 first paragraph of the specification, the substrate is a compound which can bind both to the binding domain and to the
25 catalytic domain and which is chemically converted by the

catalytic domain but not chemically modified by the binding domain. The marker substrate is a compound which is chemically different from the substrate, is chemically converted by the catalytic domain and allows monitoring of the conversion reaction. How to find such substrates for any protein to effectively determine any test compound is not seen.

An example where the enzyme is collagenase, the substrate is Type II collagen and a single specific marker substrate is presented as described in claim 3.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
 2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
 3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
 4. The nature of the invention is complex and unpredictable.
 5. State of the prior art indicates that most related substances are not effective for the claimed functions.
 6. Level of predictability of the art is very unpredictable.
 7. Breadth of the claims encompasses an innumerable number of compounds.
 8. The level of one of ordinary skill in this art is variable.
- In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 1 and 3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The newly added limitation to claim 1 of the test substance inhibits or acts as a ligand of a binding domain renders the claims as presented indefinite. On page 1 last full paragraph of the specification bridging to page 2, ~~the~~ a catalytic domain of a protein or enzyme is an amino acid sequence which binds and chemically converts a substrate. A binding domain of a protein or enzyme is an amino acid sequence which binds a substrate reversibly. When searching for inhibitors or ligands of complex proteins, usually inhibitors of the catalytic domain are found, because said inhibitors lead to a reduction in the chemical conversion of the substrate. It is substantially more difficult to find inhibitors for the binding domain. ~~the~~ On page 2, a method for performing this assay is described. If a test substance binds essentially reversibly or irreversibly to the binding domain of the protein, it may be regarded as an inhibitor of the binding domain of the protein. The claims as written do not perform the above method and therefor would not determine the activity of a substance to the binding domain specifically.

Present claim 1 will not perform the method of the preamble because as stated on pages 2 and 6 of the present specification:

1. The protein must have at least one catalytic domain and at least one binding domain;
- 5 2. The marker substrate must bind to the catalytic domain to be converted; and
3. The substrate must bind to the catalytic domain AND to the binding domain.

These features are not claimed and introduce confusion regarding
10 if something can bind only to the catalytic domain and not to the binding domain or if the substance can be catalyzed without anything binding to the binding domain.

Any inquiry concerning this communication or earlier
15 communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the
20 examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to
25 patent application information 7 days per week, or for filing

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applications electronically, please visit our website at
www.uspto.gov and click on the button Patent Electronic Business
Center for more information.

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